Appendix 5: Colm Hennessey – Final Report

The witness statements included with this report were sent to those interviewed by Mr Hennessy for comment and although some changes were suggested these did not substantially change the report and have not been reviewed by CH.

Report prepared for Heart of England NHS Foundation Trust

Introduction:

I am a Consultant General Surgeon with a special interest in breast surgery. Since 1995 I have been based at the North Tees and Hartlepool NHS Trust as a consultant surgeon, having previously trained as a senior registrar in the Northern Region. My practice includes oncoplastic surgery and I have been the QA Breast Screening Surgical Director for the North East and Yorkshire since 2000.
Through the Association of Breast Surgery at BASO, I was approached by Mr Ian Cunliffe, Medical Director of the Heart of England NHS Foundation Trust, to act as eternal reviewer in an investigation being undertaken by the trust into the clinical practice of a Consultant Breast Surgeon. After arranging cover for my absence from North Tees I agreed the process of the investigation with Mr Cunliffe. My investigation consisted in a number of meetings with professional colleagues at Heartlands and Solihull Hospitals and reviewing cases identified by the trust.
I visited the trust on 12th, 13th and 29th of November 2007. Meetings with colleagues on these days included the following: Mr Ian Cunliffe, Dr Rex Polson (Consultant Gastroenterologist and Case Investigator), Mr Misra Budhoo (Clinical Director Surgery), Drs Andrew Stockdale and Indy Fernando (Consultant Clinical Oncologists), Dr Chris Fletcher (Consultant Radiologist), Drs Peter Colloby and Bruce Tanchel (Consultant Pathologists), Mr Bala Balasubramanian (Consultant Surgeon), Mr Hemant Ingle (Consultant Surgeon), Mrs Claire Bate (Breast Care Nurse), Mr Alan Jewkes (Consultant Surgeon), Mrs CC Kat (Consultant Plastic and Reconstructive Surgeon) and Mr Ian Paterson (Consultant Surgeon). A discussion with Mr Mark Wake, Lead Cancer Clinician took place by phone.
Case note review took place on 12th, 13th, 17th and 29th of November 2007. Details regarding the surgery and histology were recorded. Cases were identified by Drs Stockdale and Fernando and Mr Ingle. Mr Bala indicated some cases that he had issues with but no details were given for these.
I was advised by Dr Rex Polson that the concerns were raised related to the following:

4. Incomplete mastectomies are being undertaken,
5. Patients are being recommended for breast reconstructive surgery when this is not clinically appropriate.
6. A male patient was inappropriately recommended for mastectomy.

The investigation also included an assessment of recurrence rates after mastectomy in the cases identified by colleagues.
In addition I was advised by Dr Polson that further allegations regarding the personal conduct of Mr Paterson was being investigated by the trust.

Case Review: for details see Appendix 1

The review of case notes took place relating to case notes identified by Drs Fernando and Stockdale and Mr Ingle. In total 63 cases were identified, 2 of which were not reviewed. A number of cases were identified by more than one clinician. Further cases have been raised by Dr Stockdale; these were not reviewed, as the issues were similar to those covered in the cases outlined above.

The 61 cases reviewed are summarised in a separate file, with a conclusion drawn for each. These conclusions are made based predominantly on pathology reports, operation notes, imaging records, photographic records and evidence from correspondence in letters and in oncology records from the notes. Having met with Mr Balasubramanian, Mr Budhoo, Dr Stockdale, Dr Fernando and Mr Ingle I am of the opinion that their clinical impressions about the issue of residual breast tissue are valid. It is possible that some of the cases simply have residual subcutaneous fatty tissue, as indicated by Mr Paterson (IP). However the cases where shaves were taken at mastectomy and where DCIS or invasive cancer were subsequently found at further surgery after mastectomy raise concerns that other similar cases may arise in the future. This is clearly the concern of the oncologists.

Of the 61 cases reviewed 7 were not considered to have a problem. The remaining 54 cases raise some issues. I have obviously not carried out a clinical examination relating to any of these patients and therefore have to accept the evidence in the clinical notes. According to the case notes 32 cases had clinical evidence of residual tissue after a mastectomy. Fifteen of these had further surgery to excise tissue after a mastectomy. In a number of cases a substantial amount of tissue was excised at the second and occasionally subsequent operations. In seventeen cases oncologists, and others, record their opinion about residual tissue based on clinical exam or imaging.

Twenty eight cases had shaves taken at mastectomy, with at least 5 having "deep" shaves. IP indicates that shaves are taken from the subcutaneous tissue closest to palpable tumour. This practice is not fully explained by the histology findings and certainly there should be no breast tissue at the deep margin.

Thirty cases had excision margins involved after mastectomy. These constitute the cohort of patients at greatest risk of local recurrence and subsequent risk of dying from their disease. Recurrence was identified in 11 of the 54 cases. One case had advanced disease at the time of presentation. A second case had evidence of residual breast tissue and developed recurrence, which is likely to be due to the location of the original cancer rather than residual tissue. A third case had surgery in 1996 by another surgeon before recurrence developed in 2005.

CC Kat was involved with 21 of this series. She was involved in reconstructing 3 patients with locally advanced disease. Two further patients were seen but rejected for reconstruction. Four have been referred for delayed reconstruction during 2007 and are awaiting their surgery. Two patients had delayed reconstruction. Of the 11 patients undergoing immediate reconstruction at the time of mastectomy 4 have developed local recurrence. Clearly the policy regarding reconstruction should have the full support from the MDT. It is obvious that in some of these cases there was conflict within the MDT.

The issues relating to the male patient indicated by Dr Polson are complex. From the case notes it would appear that Mr Ingle was entirely correct to carry out a core biopsy for gynaecomastia rather than a mastectomy. The correspondence relating to this matter indicates that the patient was quoted a price for a mastectomy rather than proceeding to a core biopsy. Mr Ingle is clear about what the patient has described. Mr Paterson suggests that the issue of the quote for the procedure was an administrative error.

Margins and Shaves:

At mastectomy it is expected that excision margins will be complete. It is not possible to guarantee that 100% of the breast tissue has been removed; however with careful dissection along tissue planes virtually all breast tissue should be removed. Where the margins are clinically or radiologically close neo-adjuvant therapy (chemo or endocrine) may be considered appropriate by the MDT. Clearly mastectomy should take all the tissue down to the pectoralis muscle. Histological deep margin involvement by invasive cancer or DCIS cannot therefore be improved upon without excision of the pectoralis and is commonly treated by adjuvant radiotherapy.

Radial margin involvement increases the risk of local recurrence and therefore increases the risk of subsequent metastatic disease. Radiotherapy cannot fully compensate for residual disease or residual tissue after a mastectomy.

The practice of taking shaves as part of a mastectomy is difficult to understand. If a mastectomy is carried out correctly, by dissecting along the plane between the subcutaneous fat and breast fat, there should not be any residual breast tissue to be shaved. There does not appear to be any justification for taking deep shaves. At least 5 cases in this series of patients had deep shaves. Despite discussion at length with IP I could not find an adequate justification for this practice. Inferior and superior shaves

suggests that there may be further at risk breast tissue within the superior or inferior flaps at mastectomy.
If there are doubts about the excision margins neo-adjuvant therapy should be considered rather than shaves. The practice of taking shaves raises doubts for the oncologists and gives rise to concerns about the risk of local recurrence. I have not found any reference to this procedure in the medical literature.
Residual breast tissue in patients, who have a mastectomy for DCIS, with or without reconstruction, is a major concern and risks recurrence. Recurrence in these patients is commonly invasive. What should have been a curative operation becomes a life threatening situation. Of the 54 cases reviewed 12 had mastectomies with DCIS involving margins of excision. Three of these patients have developed local recurrence. In 2 patients their recurrence was invasive, after what should have been a curative mastectomy for DCIS. IP did not have an explanation for these cases.
Mr Paterson indicated that he had written a paper relating to shaves taken at mastectomy, which was due to be published in 2008 in "the Breast Journal". He indicated that Mr Balasubramanian was co-author. This is a little surprising in that Mr Balasubramanian raised concerns about the use of shaves at mastectomy and did not mention the paper. This paper was subsequently reviewed (Appendix 14).

Residual Tissue:

There is clinical, radiological, photographic and histological evidence of residual tissue left on the chest wall after mastectomy. A variety of clinicians have described residual tissue. Thirteen of the 54 patients have radiological evidence of residual tissue, form follow-up investigations or from planning CT prior to radiotherapy. There are also photos taken prior to inclusion into the SCRAB radiotherapy trial or those requested by Mrs Kat prior to delayed reconstruction, which suggest that there is residual tissue.
The clinicians involved in reviewing these patients in my view are entitled to come to the conclusion that some, if not all, of these patients have residual breast tissue. The description by oncologists of the residual tissue as indicating that the patient had a partial mastectomy certainly in a significant number of cases seems justified. Photos and histology indicate substantial breast tissue after a mastectomy. Mr Paterson suggests that patients are very happy with the outcome of what he calls a "cleavage sparing mastectomy". I am sure that this is correct, however if there is residual breast tissue some of these patients are at risk of recurrence. I could not find any evidence that these patients were consented for a cleavage sparing procedure. I cannot find any description of this procedure in the medical literature.
It is also suggested by Mr Paterson that CCK would remove any residual breast tissue at the time of reconstruction. She, however, indicates that she does not get involved in any way with the oncological treatment and that she simply acts as a technician. She indicated that she does not review the pre or post operative histology relating to reconstruction cases.

Multidisciplinary Team:

Clearly many of the issues raised as part of this investigation relate to the functioning of the MDT. It is unfortunate that the members concerned were not able to resolve matters within the MDT.
Discussions, regarding the use of mastectomy shaves and margins of excision, give rise to significant difficulties. Assumptions are made that shaves are providing clear margins. It may not always be clear to the oncologists where these samples have been taken from.
The majority of the members of the MDT interviewed felt that it was not working well and a number felt that the status quo was completely unacceptable.
On occasions oncology has referred cases back to the surgeon for further excision after a mastectomy. The case review and the WMCIU data indicate the number of cases undergoing further surgery after a mastectomy.

Meetings with Professional Colleagues:

Meetings with professional colleagues took place as outlined above. Notes were taken by a representative from the HR department. Colleagues from surgery and oncology indicated their knowledge of the issues under review. For many the issues being addressed were very difficult. It was clear that the working relationships had been unsatisfactory for some time. Many, including Mr Paterson, felt that the MDT was dysfunctional.
Drs Stockdale **(Appendix 3)** and Fernando **(Appendix 4)** gave written details and went through case notes, scans and photos highlighting their concerns about residual breast tissue, excision margins and the risk of recurrence. The cases highlighted above were discussed. The working relationships within the MDT were clearly of great concern to them and they both found the present situation was unacceptable. They both indicated that a meeting had taken place relating to these issues in December

2003 and produced data relating to an audit in 2003 which are relevant to some of the issues currently under investigation. Mark Wake **(Appendix 12)** as the lead cancer clinician for the trust was involved in meeting those involved at the time and he indicated that the agreed follow-up audit relating to excision margins did not take place. But he only became aware of this earlier this year.
In the meeting with Mr Paterson **(Appendix 13)** and his MDU advisor we did not discuss the interpersonal aspects of the inquiry. We did however discuss the issue of the appointment of a third surgeon to the unit. IP indicated that he was in full agreement with the appointment of an additional surgeon to develop the oncoplastic service and support Mrs Kat. Clearly there are issues relating to this matter that are subject of investigation by Dr Polson. Other colleagues did identify that the unit had a number of locum and other short term appointments leading up to the appointment of Mr Ingle. IP indicated that he had a paper due to be published relating to excision margins. This was reviewed later on behalf of the trust **(see Appendix 14).**
Claire Bate **(Appendix 7)** was not aware of the concerns expressed by the oncologists and surgical colleagues. She was very supportive of Mr Paterson and the volume and quality of his care to patients.
Mrs Kat **(Appendix 11)** as indicated above said that she did not get involved in the oncological aspects of breast surgery. We discussed the cases where reconstruction issues were raised. She assumed that all were referred with support from the MDT. She also indicated that she welcomed Mr Ingle's input into the oncoplastic service and had no problem working with him.
Mr Balasubramanian **(Appendix 8)** and Mr Ingle **(Appendix 5)** indicated their experience of reviewing some of Mr Paterson's patients. They had reservations about completeness of excision in some of the cases and both were concerned about the practice of cavity shaves at mastectomy.
Drs Colloby **(Appendix 6 b)** and Tanchel **(Appendix 6 a)** were aware of the tensions within the MDT but did not have strong views regarding the clinical issues raised by the investigation. They were aware of a previous audit in 2003 where concerns were raised about excision margins. It was clear from other documents that plans were made for a prospective audit. They indicated that because of a change in Mr Paterson's practice, with regard to cavity shaves, after the original audit that the subsequent audit was not carried out. They indicated that some of the mastectomy shaves are difficult to orientate, but many have a suture orientating the shave. They were baffled by the practice of taking shaves at mastectomy.
Dr Fletcher **(Appendix 10)** was concerned about a number of the above cases and was clear that his radiography staff were aware that a small number of patients after mastectomy had residual tissue which required mammography. He was also concerned about the MDT.
Mr Budhoo **(Appendix 2)** and Mr Jewkes **(Appendix 9)** had very little extra to add, however both had seen patients recently at the request of colleagues and agreed that there were concerns.

Peer Review and Breast Screening QA visits:

Through the Trust data was received from the WMCIU. This data indicates that IP was responsible for 1351 patients who had treatment for breast cancer from 2000 to 2006. One patient required 5 operations, 4 patients required 4 operations and 31patients required 3 operations. Patients had their operations in several hospitals, 810 in Solihull, 206 in Heartlands, 4 in Good Hope and 328 in the private sector (predominantly Parkway). Of the 1351, 38 patients had what appears to be a procedure to excise more breast tissue after a previous mastectomy. The data sheet does not include pathology information, particularly the margins of excision or whether or not shaves were taken.
Sixteen of the 38 cases were recorded as having developed recurrence after mastectomy. The majority of these occurred between 2 and 5 years post mastectomy. There were however 3 cases where recurrence appeared within 10 months.
Twenty two patients had a breast conserving operation following a mastectomy and axillary surgery. The majority of these occurred within a month of the original operation, suggesting that they were carried out because of doubt about margins. Two of the cases had their second operations carried out 6 weeks after the original mastectomy.
Comparative data relating to the number of patients undergoing repeat operations may be available from the WMCIU.

QA visit April 2004:

The report of the Breast Screening QA meeting in 2004 indicates that Mr Paterson along with other breast surgeons in the region discussed a number of key issues. A number of issues may be of relevance to this investigation. It was agreed that an audit should be initiated to explore the reasons for the high open biopsy rate and the relatively large number of cancers diagnosed by open biopsy at Solihull Hospital. The issues of orientation of specimens and excision margins were discussed.

Surgeons were encouraged to adopt NHSBSP guidelines in orientating specimens for pathology. This may not have related to Solihull. The minutes also emphasise the importance of excision margins particularly for DCIS, where recurrence is directly related to grade and excision margin. It has therefore been recommended that all of the multi-disciplinary teams within the Warwickshire, Solihull & Coventry Breast Screening Service should agree a policy regarding margin status, and that a copy of this policy should be sent to the QA reference centre within three months. I presume this was carried out. The minutes also comment on issues relating to the MDT. The QA team was assured that all breast screening cases were discussed in a multi-disciplinary forum. However, as has been noted in the breast care nursing section of this QA report, several organisational issues in relation to the multi-disciplinary team meeting at Solihull Hospital needed to be addressed. The Director of Breast Screening advised that he had written to the Medical Director at Solihull Hospital on two occasions, expressing concern over the organisation of the multi-disciplinary team meeting. A recommendation was made that the operation of the multi-disciplinary team meetings held at Solihull Hospital be reviewed again after 3 months. The areas reviewed should include the three-way video link, the issue of MDT co-ordinator support and the possibility of separating screening and symptomatic cases. As part of the review process, it was also recommended that members of the regional breast screening QA team should attend a multi-disciplinary team meeting in Solihull, so that they can gain a fuller understanding of the issues raised at the QA team visit. It was agreed that the issues relating to the multi-disciplinary meeting should be raised with the Cancer Peer Review Team as many were outside the remit of the QA team as they concerned symptomatic rather than screen detected breast cancers.

Additional Breast Screening QA team visit 14th Sept 2004:

An additional Breast Screening QA team visit took place on 14th Sept 2004 attended by majority of the MDT members interviewed for this investigation. The review team included Gill Lawrence, Olive Cairns, Tim Bucknell and Margaret Casey. The summary in the report from this visit indicated that some improvements had taken place since April and that the appointment of the new MDT co-ordinator and the improved communication link were already having a positive effect on the working of the MDM. However, having reviewed the operation of the multi-disciplinary team, a number of observations and suggestions were made by members of the team to further improve the effectiveness of the Solihull breast unit. As a number of these issues apply mainly to the symptomatic service this information was to be conveyed to the Cancer Peer Review Team. A number of recommendations were made relating to the workings of the MDT to enhance the effectiveness and efficiency.

QA Visit 26th April 2007:

The pathology section of the report indicates that the recommendation relating to an audit of the orientation of specimens had not been completed. A recommendation was therefore made that a prospective audit of specimen be carried out within six months of the QA team visit. The number of specimens (localisation biopsies, wide local excisions, and other specimens that should be orientated) without orientation markers should be counted and compared to the total number of such specimens for both screening and symptomatic breast cancers. The consultant surgeon who sent the specimens should also be recorded. No mention is made in the report is made by pathology regarding the functioning of the MDT.

At this visit the trust was represented at the surgical meeting by Mr Balasubramanian, Mr Ingle and Mr Patterson. The following paragraph is extracted from the report. "Overall, the surgical management of the patients is very good and the review of the individual surgeon's data was satisfactory. There were one or two small aberrations relating to mastectomy rates and re-operation rates. The QA team believes however that these are due to small numbers and are not of great concern at present. The QA team will review these rates in next year's data."

Peer Review 2005:

The breast MDT performed well and no comment is made about the functioning of the MDT. All of the measures were met except for:

2B-127 and 2B-128 Relating to specialist study being carried out by nurse members of the MDT.

2B-142 to 144 Relating to guidelines.
2B-145 Relating to Herceptin
2B-146 Lack of evidence that the MDT had adopted NSSG guidelines relating to early breast cancer follow-up and 2B-147 Agreement regarding minimum data set
2B-149 93% of data submitted to cancer registry 2B-152 and 2B-153 relating to audit and trials.
In addition comments were made regarding a number of measures including:
The failure of the lead clinician to attend the NSSG; The video-link between Coventry and Solihull; and Core MDT clinician membership having 50%of their time devoted to breast cancer.

Conclusions:

Following my case note review, meetings with colleagues and review of data provided by the trust I feel that there are justifiable concerns relating to three issues as indicated by Dr Polson. The particular concerns about excision margins and risk of recurrence are in my opinion justified. The practice of mastectomy shaves seems to add to the concerns regarding this issue. It is clear that Mr Paterson wishes to provide the best possible cosmetic outcome from a mastectomy and clearly a tidy scar and some cleavage are popular with patients. It is obviously impossible to prove whether or not all residual chest wall tissue after mastectomy contains breast glandular tissue. My surgical interpretation of the imaging reports and hard copy supports the concern raised by oncology and surgical colleagues. Not all of the features on the images can be put down to post-operative scarring.
Concerns about the risk of recurrence have not been alleviated since the audit in 2003. There are clearly faults within the team and within the organisation in not addressing these concerns. The MDT itself is at the heart of the problem. Many of those interviewed felt that the MDT process was to some extent being circumvented and for some of the cases inappropriate decisions were being taken.
The case of the male patient does raise concern, as it would appear he was not offered a core biopsy. The relevant case notes relating to this patient were in the private sector and therefore not subject of review. However, the correspondence between Mr Paterson and Mr Ingle does not address the issue fully and simply passes the matter off as a clerical error. Mr Ingle is clear about the information given by the patient.
It should be acknowledged at this stage that Mr Paterson has in the past and continues to carry out a very substantial volume of the cancer work within the unit. Clearly now that there are 3 surgeons within the unit there is greater scope for sharing the workload. All of the surgeons should carry out surgery to an agreed policy.
It should be possible to repair the fractured relationships within the MDT; this would be in the best interest of the unit, the trust and more importantly of the patients.

Recommendations:

g. A thorough review of the MDT needs to take place involving all members of the team, looking at data and functioning within the unit.
h. Specific attention should be paid to the issue of shaves at mastectomy, the number of mastectomies with margins involved and why. Noting particularly the size and location of cancers and whether or not there is multifocality.
i. The practice of shaves at mastectomy should cease. The MDT needs to be confidant that a mastectomy means as close to 100% as possible of the breast tissue is removed. If all of the breast tissue is removed a flat chest should be achieved, therefore cleavage sparing mastectomy will not be carried out.
j. The dysfunction relationships within the MDT need to be repaired. A successful outcome is only likely to be achieved through significant compromises. It is possible that some improvement can be achieved through facilitated meetings.
k. The leadership within the MDT needs to have the support and strength to deal with the difficult situations encountered.
l. Reconstruction decisions should be taken to the MDT and a detailed review should take place of immediate reconstructions over the past 3 years.
m. The WMCIU data should be reviewed with regard to margins of excision and shaves. It may require going through the histology reports. Data relating to those with

recurrences and those identified as having a second operation after a mastectomy should also be reviewed.

n. Treatment policies relating to breast cancer, including: Mastectomy, Excision Margins, Reconstruction and Neo-Adjuvant therapy should be formally agreed by the MDT. These policies should then be presented in an audit annually.

Mr Colm Hennessy
21st January 2008